



Food and Drug Administration
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Biocomposites Ltd
Mr. Simon Fitzer
Keele Science Park
Keele
Staffordshire
ST5 5NL
United Kingdom

January 23, 2015

Re: K141830

Trade/Device Name: Stimulan Kit/Stimulan Rapid Cure
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: December 22, 2014
Received: December 24, 2014

Dear Mr. Fitzer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K141830

Device Name

Stimulan Kit/Stimulan Rapid Cure

Indications for Use (Describe)

Stimulan Kit/Stimulan Rapid Cure is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or created from traumatic injury to the bone. Stimulan Kit/Stimulan Rapid Cure is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., extremities, pelvis, and posterolateral spine). Stimulan Kit/Stimulan Rapid Cure provides a bone graft substitute that resorbs and is replaced with bone during the healing process. Stimulan Kit/Stimulan Rapid Cure is biodegradable and biocompatible and may be used at an infected site.

To fill a bone void or defect created by:

- surgery
- a cyst
- a tumour
- osteomyelitis
- traumatic injury

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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510(k) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR807.92(c), the following information serves as a Summary of Safety and Effectiveness for the use of Stimulan Kit/Stimulan Rapid Cure.

- 1. Submitted by:** Biocomposites Ltd
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Staffordshire
ST5 5NL
England

Date: January 23, 2015

Contact Person: Simon Fitzer
Regulatory
Tel: +44 (0) 1782 338580
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- 2. Proprietary Name:** Stimulan Kit/Stimulan Rapid Cure

Common Name: Bone Void Filler

Classification: 21 CFR 888.3045 – Class II

Product Code/Panel: MQV/Orthopedic
- 3. Primary Predicate Device:** K021551- Stimulan Kit

4. Device Description

Stimulan Kit/Stimulan Rapid Cure are indicated to be implanted into defects not intrinsic to the structural stability of the skeletal system. Stimulan Kit/Stimulan Rapid Cure are biocompatible and may be implanted at an infected site. Stimulan Kit/Stimulan Rapid Cure are presented as a powder and mixing solution which when mixed together form a paste which may be injected, digitally implanted or applied to the mold provided to produce pellets.

5. Materials

Stimulan Kit/Stimulan Rapid Cure are manufactured from medical grade calcium sulfate. Stimulan Kit/Stimulan Rapid Cure resorbs and is replaced by bone during the healing process.

6. Intended Use

Stimulan Kit/Stimulan Rapid Cure is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or created from traumatic injury to the bone. Stimulan Kit/Stimulan Rapid Cure is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., extremities, pelvis, and posterolateral spine). Stimulan Kit/Stimulan Rapid Cure provides a bone graft substitute that resorbs and is replaced with bone during the healing process. Stimulan Kit/Stimulan Rapid Cure is biodegradable and biocompatible and may be used at an infected site.

To fill a bone void or defect created by:

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- a tumour
- osteomyelitis
- traumatic injury

7. Technological Characteristics Comparison

The technological characteristics have not changed as a result of the labeling modification.

8. Substantial Equivalence – Non – Clinical Evidence

Design controls were implemented following risk analysis. No new risks were identified demonstrating that the modified device is substantially equivalent to the predicate device.

9. Substantial Equivalence – Clinical Evidence

Clinical performance data was not required as the labelling modifications do not affect the safety and effectiveness of the modified device.

10. Substantial Equivalence – Conclusions

The labeling modifications made do not raise any new concerns regarding safety and effectiveness. The information provided supports that the modified Stimulan Kit/Stimulan Rapid Cure is substantially equivalent to the predicate device.